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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Shaharyar Khan

GNC 0001

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04/09/2010

Pabst Patent Group LLP

1545 PEACHTREE STREET NE

SUITE 320

ATLANTA, GA 30309

EXAMINER

LI, QIAN JANICE

ART UNIT

PAPER NUMBER

1633

MAIL DATE

DELIVERY MODE

04/09/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/561,829	KHAN, SHAHARYAR	
	Examiner	Art Unit	
	Q. JANICE LI	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 February 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 114,116-119,121 and 128 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 114,116-119,121 and 128 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 December 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The amendment and reply filed 2/16/2010 are acknowledged.

Election/Restrictions

Applicant requested that claim 116 be joined with group I arguing that bacteriophage is a species of a virus.

It is noted the amended claim 114 describes a composition distinct from the original presented. Original claim 114 describes a composition comprising a recombinant polypeptide operably linked to a polynucleotide, whereas the amended claim 114 describes a composition comprising viral capsid proteins comprising a recombinant polypeptide and enclosing a polynucleotide.

Considering the restriction was set up as a linking claim format, and considering the amended claims better describes an illustrated embodiment of the specification, i.e. a modified bacteriophage, Applicant's request for rejoining claim 116 has been granted. The amended claims will be examined in this application. The restriction between the linking groups II & I is hereby withdrawn.

Claims 114, 116-118, 121 have been amended. Claim 128 is newly submitted. Claims 114, 116-119, 121, 128 are under current examination.

Unless otherwise indicated, previous rejections that have been rendered moot in view of the amendment to pending claims and new grounds of rejections will not be reiterated.

Specification

The disclosure stands objected to because it contains an embedded hyperlink and/or other form of browser-executable code (e.g. Specification, page 21, line 24; page 30, line 5). Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

The hyperlinks still exist in the newly submitted table and at page 30 of the specification.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 114, 116, 117-119, 121, 128 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are vague and indefinite because of the claim (114) recitation “wherein one or more of the viral capsid proteins comprise an organelle localization signal...”. It is unclear how a protein comprises another protein(s), and hence the metes and bounds of the claims are unclear. Further, in the context of the newly recited structure, it is unclear how the organelle localization signal comprised by the capsid proteins then expressed on an exterior surface of the vector, and hence the metes and bounds of the claims are uncertain.

For the sake of a compact prosecution, the claims have been interpreted as viral capsid proteins forming chimeras with an organelle localization signal linked to a PTD.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 114, 116-119, 121, 128 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Nakanishi et al.* (Curr Protein Peptide Sci 2003 April;4:141-150) in view of *Del Gaizo et al.* (Mole Ther 2003 Jun;7:720-30, IDS).

Nakanishi discloses a composition comprising a lambda phage viral particle, which encapsulates (enclosing) a recombinant polynucleotide encoding heterologous marker polypeptides, HIV Tat protein transduction domain and a nuclear (organelle) localization signal derived from SV40 T antigen (NLS e.g. the abstract, and §4 & 5), wherein the capsid proteins of the lambda phage (such as the D protein, gpD, see paragraph bridging pages 142-3) can form chimeras on its surface with foreign peptides (peptide display). *Nakanishi* teaches the recombinant lambda phage complex comprising PTD and NLS can remarkably facilitate the delivery of marker genes across two major barriers of gene delivery, i.e. the cell membrane and the nuclear membrane. *Nakanishi* does not teach operably link the NLS and PTD.

Del Gaizo supplemented the deficiency by establishing it was well known in the art to operably link PTD and OLS functional peptides for the purpose of targeted cell delivery. *Del Gaizo* teaches a composition comprising a polynucleotide encoding a recombinant fusion protein having a mitochondria localization signal sequence (mitochondrial malate dehydrogenase signal sequence, mMDH) linked to a TAT protein transduction domain, and a marker protein eGFP (e.g. figure 1). *Del Gaizo* teaches expressing the fusion protein in various cells *in vitro* and *in vivo* (e.g. figures 2, 4, 6).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the lambda phage complex taught by *Nakanishi* by incorporating the polynucleotide as taught by *Del Gaizo* in the phage complex as taught by *Nakanishi* with a reasonable expectation of success. The ordinary skilled artisan would have been motivated to do so because the same complex would overcome two barriers of cell delivery of compounds. Thus, the claimed invention as a whole was *prima facie* obvious in the absence of evidence to the contrary.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Q. JANICE LI** whose telephone number is **571-272-0730**. The examiner can normally be reached on 9 AM -7:00pm, Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Joseph Woitach** can be reached on **571-272-0739**. The **fax** numbers for the organization where this application or proceeding is assigned are **571-273-8300**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

For all other customer support, please call the USPTO Call Center (UCC) at **800-786-9199**.

*/Q. JANICE LI/
Primary Examiner, Art Unit 1633*